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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/844,628

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Nicolaas M. Lokhoff

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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MS-LC340
MINNEAPOLIS, MN 55432-5604

EXAMINER

BRADFORD, RODERICK D

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/844,628

Applicant(s)

LOKHOFF ET AL. **MF**

Examiner

Roderick Bradford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Figure 6 is not included in the Brief Description of Drawings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 11, 14, 15 and 20-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 3, "stiffening member" is vague because it is inferentially included and needs to be positively recited.

Referring to claim 11, "a sensor" is vague because it is inferentially included and needs to be positively recited.

Referring to claim 14, "respective conductor" is vague because it is inferentially included and needs to be positively recited.

Referring to claim 15, "second ring" is vague because it is inferentially included and needs to be positively recited.

Referring to claim 20, "methods" is vague. It is suggested by the examiner to use "steps" and "whereby" is vague. It is suggested by the examiner to use "wherein".

Referring to claims 21 and 22, "methods" is vague and it is suggested by the examiner to use "the step of advancing".

Referring to claims 23-30, "method" should be changed to "step". Also in claim 26, "Claim 25" should be replaced with "delivering electrical stimulation" and in claim 27, "delivery" should be changed to "deliver".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 5, 7-11, 14, 16, 19, 20, 21, 25, 28, 29, 31 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. U.S. Patent No. 5,716,390 in view of Russink et al. U.S. Patent No. 5,522,876.

Referring to claims 1, 20 and 31, Li discloses a an implantable device

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comprising: an elongated body having a proximal and distal end, the distal end including an inner lumen (abstract), a helix residing within the inner lumen and adapted to be extended beyond the distal end of the elongated body (abstract). But Li, fails to disclose wherein at least a portion of the helix having a diameter that is larger than the diameter of the elongated body. However, Russink discloses wherein at least a portion of helix having a diameter that is larger than the elongated body. (column 2, lines 17-19) as a means to displace from the immediate electrode the trauma caused to the heart wall be the helix.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Li to include wherein at least a portion of helix having a diameter that is larger than the elongated body, as taught by Russink, as a means to displace from the immediate electrode the trauma caused to the heart wall be the helix.

Referring to claim 5, Li discloses wherein the diameter of the helix is extended is substantially constant (Fig. 3).

Referring to claims 7 and 25, Li discloses further including a conductor to the helix whereby the helix may be used to deliver electrical stimulation (column 6, lines 57-60).

Referring to claims 8 and 21, Li discloses wherein the conductor is a coiled conductor configured such that the helix may be extended and retracted by rotation imparted to a proximal end of the coiled conductor (abstract).

Referring to claims 9 and 10, Russink discloses wherein the helix is formed of a super elastic material and wherein the super elastic material is a shape memory alloy (column 3, lines 18-20).

Referring to claims 11, 29 and 35, Li discloses wherein the elongated body is further coupled to a sensor to sense a physiological signal (column 6, lines 2-4).

Referring to claim 14, Li discloses further including at least one ring electrode carried on the elongated body and coupled to a respective conductor to allow for multi-polar pacing (column 1, lines 65-67 and column 2, lines 4-8).

Referring to claims 16 and 28, Li discloses further including at least one defibrillation electrode carried on the elongated body (column 4, lines 61-65).

Referring to claims 30 and 33 wherein the step includes expanding the helix to contact at least one wall of the vessel (abstract).

Referring to claim 34, and further including a ring electrode carried on the lead body (column 5, lines 19, 20).

7. Claims 2, 3, 4, 17, 22-24 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. U.S. Patent No. 5,716,390 in view of Russink et al. U.S. Patent No. 5,522,876 as applied to claims 1, 5, 7-11, 14, 16, 19, 20, 21, 25, 29, 31 and 33-35 above, and further in view of Bens et al. U.S. Patent No. 5,259,394.

Referring to claims 2, 3, 4, 17, 22-24, and 32, Li in view of Russink fails to disclose further comprising at least a portion of the helix re-assumes a compressed configuration within the inner lumen, wherein the fixation assembly includes a coupling member to interface with the stiffening member, wherein the fixation assembly includes

means to allow the helix to be extended and retracted by rotation of the stiffening member and wherein the fixation assembly includes a helical lumen to guide the helix during extension and retraction. However, Bens discloses further comprising at least a portion of the helix re-assumes a compressed configuration within the inner lumen (column 9, lines 47-51) as a means of more easily positioning the tube with in a body vessel, wherein the fixation assembly includes a coupling member to interface with the stiffening member (column 5, lines 6-17) as an alternate means of more easily rotating the helix, wherein the fixation assembly includes means to allow the helix to be extended and retracted by rotation of the stiffening member (column 6, lines 12-26 and column 9, lines 46-51) as an alternate means of more easily rotating the helix and wherein the fixation assembly includes a helical lumen to guide the helix during extension and retraction (column 3, lines 6-12) as a means to make sure that the helix is properly aligned

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Li in view of Russink to include further, as taught by Bens, comprising at least a portion of the helix re-assumes a compressed configuration within the inner lumen as a means of more easily positioning the tube with in a body vessel, wherein the fixation assembly includes a coupling member to interface with the stiffening member as an alternate means of more easily rotating the helix, wherein the fixation assembly includes means to allow the helix to be extended and retracted by rotation of the stiffening member as an alternate means of more easily rotating the helix and wherein the fixation assembly includes a helical lumen to guide

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the helix during extension and retraction (column 3, lines 6-12) as a means to make sure that the helix is properly aligned

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. U.S. Patent No. 5,716,390 in view of Russink et al. U.S. Patent No. 5,522,867 as applied to claims 1, 5, 7-11, 14, 16 and 19 above, and further in view of Struble et al. U.S. Patent No. 5,871,531.

Referring to claim 6, Li in view of Russink fails to disclose wherein the diameter of the helix when the helix is extended decreases towards a distal end of the helix. However, Struble discloses wherein the diameter of the helix when the helix is extended decreases towards a distal end of the helix (Fig. 2) as a means of fitting in smaller vessels and as a means to minimize vessel damage.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Li in view of Russink to include wherein the diameter of the helix when the helix is extended decreases towards a distal end of the helix, as taught by Struble, as a means of fitting in smaller vessels and as a means to minimize vessel damage.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. U.S. Patent No. 5,716,390 in view of Russink et al. U.S. Patent No. 5,522,867 as applied to claims 1, 5, 7-11, 14, 16 and above, and further in view of Verness et al. U.S. Patent No. 6,119,042.

Referring to claim 12, Li in view of Russink fails to disclose wherein the sensor is selected from a group of a pressure sensor, O₂ saturation sensor, a temperature sensor,

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a flow sensor, an impedance sensor, a stroke volume sensor, and a pH sensor.

However, Verness discloses wherein the sensor is selected from a group of a pressure sensor, O₂ saturation sensor, a temperature sensor, a flow sensor, an impedance sensor, a stroke volume sensor, and a pH sensor (column 5, lines 34-36) as a means to make the lead more efficient by sensing different physiological parameters.

~~It would have been obvious to one having ordinary skill in the art at the time the~~
invention was made to modify the device of Li in view of Russink to disclose wherein the elongated body is further coupled to a sensor to sense a physiological signal and wherein the sensor is selected from a group of a pressure sensor, O₂ saturation sensor, a temperature sensor, a flow sensor, an impedance sensor, a stroke volume sensor, and a pH sensor, as taught by Verness, as a means to make the lead more efficient by sensing different physiological parameters.

Referring to claims 14, 16, 28 and 34, Bens fails to further include at least one ring electrode carried on the elongated body and coupled to a respective conductor to allow for multi-polar pacing and further including at least one defibrillation electrode. However, Verness includes at least one ring electrode carried on the elongated body and coupled to a respective conductor to allow for multi-polar pacing (column 5, lines 37-43) as a means to stimulate different sections of the heart and further including at least one defibrillation electrode (12) as a means to make the lead more efficient.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Verness to include at least one ring electrode carried on the elongated body and coupled to a respective conductor to allow

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for multi-polar pacing and further including at least one defibrillation electrode, as taught by Verness, as a means to stimulate different sections of the heart and further including at least one and as a means to make the lead more efficient.

10. Claims 13, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. 5,716,390 in view of Russink et al. U.S. Patent No. 5,522,876.

~~Referring to claim 13, Li in view of Russink discloses the claimed invention~~
except for wherein the helix lumen configured to allow blood flow to continue in an unimpeded manner at an implant site within the body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Li in view of Russink, to include wherein the helix lumen configured to allow blood flow to continue in an unimpeded manner at an implant site within the body since it was well known in the art to include lumens that allow blood flow to continue unimpeded as means to prevent blood clots within the vessels.

Referring to claim 26, Li in view of Russink discloses the claimed invention except for wherein the elongated body further carries a ring electrode, and wherein the step includes delivering the electrical stimulation between the helix and the ring electrode.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Li in view of Russink to include delivering the electrical stimulation between the helix and the ring electrode since it was

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well known in the art that delivering the electrical stimulation between the helix and the ring electrode as a means to more efficiently treat the desired body tissue..

Referring to claim 27, discloses the claimed invention except for wherein the elongated body carries multiple ring electrodes, and further including the step of utilizing one or more predetermined ones of multiple ring electrodes to deliver electrical stimulation to one or more locations within the body.

It would have been obvious to one having ordinary skill at the time the invention was made to modify the device as taught by Li in view of Russink wherein the elongated body carries multiple ring electrodes, and further including the step of utilizing one or more predetermined ones of multiple ring electrodes to deliver electrical stimulation to one or more locations within the body since it was well known in the art to provide multiple ring electrode as a means of simultaneous provide stimulation to different body tissue.

11. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. U.S. Patent No. 5,716,390 in view of Russink et al. U.S. Patent No. 5,522,876 and in view of Bens et al. 5,259,394 as applied to claims 1, 5, 7-11, 14, 16 and 19 above, and in further view of Doan et al. U.S. Patent No. 5,456,708.

Referring to claim 18, Li in view of Russink and Bens fails to disclose wherein the helical lumen includes a seal adapted to prevent the ingress of fluids. However, Doan discloses a helical lumen includes a seal adapted to prevent the ingress of fluids (column 3, lines 14-17) as a means to stop body fluids from entering the lead body.

It would have been obvious to one having ordinary skill in the art at the time the

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invention was made to modify the device of Li in view of Russink and Bens to include a helical lumen includes a seal adapted to prevent the ingress of fluids, as taught by Doan, as a means to stop body fluids from entering the lead body.

Allowable Subject Matter

12. Claim 15 is objected to as being dependent upon a rejected base claim, but ~~would be allowable if rewritten in independent form including all of the limitations of the~~ base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

R. Bradford

R.B. 2/24/03
February 24, 2003

~ C
GEORGE R. EVANISKO
PRIMARY EXAMINER

2/24/3